

Protection & Advocacy, Inc.

ADMINISTRATION

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August 4, 2004

Food and Drug Administration, Dockets Management
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Email: fdadockets@oc.fda.gov

Re: Docket Number 2003P-0555

Dear Sir or Madame:

I am writing on behalf of the Protection & Advocacy, Inc. (PAI) Board of Directors. As you may know, PAI is the agency designated by federal law to protect and advocate for the rights of Californians with disabilities. Last year, PAI provided advocacy assistance to 4,617 individuals with psychiatric disabilities. PAI's Board approved priorities including protecting the legal rights of individuals with disabilities and ensuring personal autonomy the right to make informed choices and give informed consent to medical procedures.

In 1979 the FDA issued a final rule placing the ECT device in the highest risk class of medical devices. This was done after recognizing serious health risks, notably brain damage and memory loss, in the use of ECT. A device with a class III rating merits a safety review. We recently learned that the FDA is considering reclassifying ECT from a class III to a class II device. Of particular concern is that it appears that the FDA is taking this action on its own initiative and on the basis of a literature review. These unprecedented actions taken without the opportunity for public input leave serious questions about the FDA's motives and process.

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